

R E M A R K S

Applicant herein response to the office action mailed January 11, 2002.

Applicant have amended claims 43, 55, 56, 62, 73 and 75 to correct informalities, which obviates the indefiniteness rejections made by the examiner. Applicant have added claims 76-81. Support for the amended and added claims can be found throughout the specifications. See, for instance, Example 1. Applicant also have canceled claims 50, 63-72 and 74 without prejudice or disclaimer of the subject matter recited therein, and Applicant reserve all rights to such subject matter. Upon entry of this amendment, claims 43-62, 73, and 75-81 will be pending. Applicant also provides a copy of power of attorney and change of correspondence address. The office action is discussed below.

The claimed invention is supported by the specification

On pages 3-4 of the office action, the examiner rejected claims 43 and 62 due to the recitation of "stabilizing." Applicant have amended the claims to recite "adsorbing" instead of stabilizing. Support for the amendment can be found throughout the specification. See, for instance, page 9, third full paragraph and Example 5. Accordingly, Applicant requests withdrawal of the rejection.

The claimed invention is not taught by Chandra or Evans

On pages 6-7 of the office action, the examiner rejected claims 43-52 and 55-63 as anticipated by the Chandra patent. On pages 8-9, the examiner rejected claims 43-48, 50-55, 57-60, 62-64 and 74 as anticipated by the Evans patent or PCT. Applicant respectfully traverses these rejections.

Applicant notes that in order to reject a claim under 35 USC § 102, the examiner must demonstrate that each and every claim term is contained in a single prior art reference. See *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 18 USPQ2d 1001, 1010 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 90 (Fed. Cir. 1986); see also MPEP § 2131 (August 2001). Claim terms are to be given their plain meaning as understood by the person of ordinary skill in the art, particularly given the limitations of the English language. See MPEP §§ 707.07(g); 2111.01 (August 2001). Claims are to be given their broadest reasonable interpretation consistent with Applicant's specification. See *In re Zletz*, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (holding that claims must be interpreted as broadly as their terms **reasonably** allow); MPEP § 2111 (August 2001).

Not only must the claim terms, as reasonably interpreted, be present, an allegedly anticipatory reference must enable the person of ordinary skill to practice the invention as claimed. Otherwise, the invention cannot be said to have been already within the public's possession, which is required for anticipation. See *Akzo, N.V. v. U.S.I.T.C.*, 1 USPQ2d 1241, 1245 (Fed. Cir. 1986); *In re Brown*, 141 USPQ 245, 249 (CCPA 1964).

As explained in its abstract, the Chandra patent discloses adsorbing Factor IX to a solid phase and then treating it with just a detergent solution. In contrast, the claimed invention, as clarified herein, incubates the biological material in the presence of the alkyl phosphate-free detergent solution that contains at least one eluotropic salt such that proteins can be desorbed and the microorganisms and pyrogens inactivated. Applicant's invention provides an elegant approach that is effectively inactivates while

preserving labile proteins contained in the biological material, which is economical and readily practiced at an industrial scale. See applicant's specification at page 3.

Accordingly, Chandra does not teach the present invention.

The Evans patent and PCT (only the patent is cited to by the examiner) discloses a cell lysis technique for isolating DNA from cells. The Evans patent at column 2, line 22 mentions the blood as a source for suspensions of cells. The Evans approach employs harsh conditions employing chaotropic agents to disrupt proteins of cell walls to allow for the isolation of nucleic acids. Thus, Evans is concerned with protein destruction as a means to isolate DNA. The present invention, in stark contrast, is concerned with inactivating microorganisms and pyrogens in a biological material under sufficiently gentle conditions such that proteins that are not denatured can be obtained. Thus, the Evans subject matter is very distinct from the present invention, and therefore Evans cannot anticipate the claims.

Given the above distinctions, Applicant submits that Chandra and Evans do not meet the limitations of the claims, and does not enable the practice of the claimed invention. Accordingly, Chandra and Evans do not place the claimed invention in the possession of the public, and thus the rejections should be withdrawn.

***The claimed invention is not suggested by the combination of
Chandra and Evans***

On pages 10-11, the examiner rejected claims 64 and 74 (now cancelled) as obvious over Chandra. In making the rejection, the examiner states that the invention of these claims was nothing more than reversing the steps of Chandra. However, the

examiner provides no reason why the skilled person would find it desirable or necessary to reverse the Chandra steps, which renders the rejection defective from the start.

Accordingly, applicant traverses the rejection.

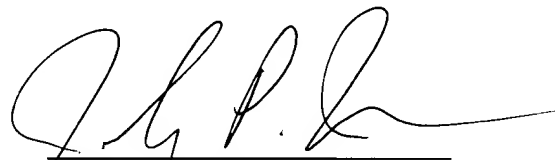
Without acquiescing in the rejection, the cancellation of claims 64 and 74 without prejudice or disclaimer moots the rejection. These claims, and others, were canceled so that applicant could focus on certain embodiments of the invention. Regardless of the cancellation, Chandra did not render these claims obvious for at least the reasons described above with regard to the anticipation rejection. Applicant therefore respectfully requests withdrawal of the rejection.

Request

Applicant submits that the claims are in condition for allowance, and respectfully request favorable consideration to that effect. The examiner is invited to contact the undersigned at (202) 912-2000 should there be any questions.

Respectfully submitted,

July 11, 2002



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Marked-up Copy of Amended Claims

43. (Twice amended) A method of inactivating microorganisms and pyrogens present in a biological material[s] comprising:

[stabilizing] adsorbing a biological material **[on] to** a solid carrier, **wherein the biological material comprises proteins; and**

incubating said biological material in the presence of an alkyl phosphate-free detergent solution, **wherein** said detergent solution **[containing] contains** at least one elutropic salt in a total concentration of at least 200 mM [**;** and

eluting said biological material from said detergent solution] , wherein during incubating said proteins are desorbed into the detergent solution to yield a suspension and said microorganisms and pyrogens are inactivated.

55. (Amended) The method according to claim 43, wherein **said** incubating is performed **[from between 10 minutes and 10 hours] for a period ranging from 10 minutes to 10 hours.**

56. (Amended) The method according to claim 43, wherein said **[wherein]** incubating is performed **[from between 1 hour and 5 hours] for a period ranging from 1 hour to 5 hours.**

62. (Twice amended) A method of inactivating microorganisms and pyrogens present in biological materials to yield a biological preparation, wherein the method [comprising] comprises:

[stabilizing] adsorbing a biological material [on] to a solid carrier, wherein the material comprises proteins;

incubating said biological material in the presence of an alkyl phosphate-free detergent solution, wherein said detergent solution [containing] contains at least one eluotropic salt in a total concentration of at least 200 mM [;

eluting said biological material from said detergent solution] , wherein during incubating said proteins are desorbed into the detergent solution to yield a suspension and said microorganisms and pyrogens are inactivated; and

purifying said [biological material eluted] proteins from said suspension [from said detergent solution] to yield a biological preparation.

73. (Amended) A [preparation] suspension prepared according to claim [1] 43.

75. (Amended) A preparation prepared according to claim [73] 62.